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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,701	01/12/2004	Terry McLean	10557/2666547	3432
30559 7590 04/09/2007 CHIEF PATENT COUNSEL SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116			EXAMINER SNOW, BRUCE EDWARD	
			ART UNIT	PAPER NUMBER
			3738	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/755,701	Applicant(s) MCLEAN, TERRY	
	Examiner Bruce E. Snow	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS; WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 101-131 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 130 and 131 is/are allowed.
- 6) ☒ Claim(s) 101-108, 110-129 is/are rejected.
- 7) ☒ Claim(s) 109 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>herewith</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

The Final Office action dated 1/30/07 has been withdrawn and a new action follows. Kate Hart indicated no response and no claim amendments has been or will be submitted prior to this Office action.

DETAILED ACTION

Response to Arguments

Applicant's amendments and arguments filed 11/15/06 have been fully considered.

Election/Restrictions

As previously noted by the Examiner, applicant's election with traverse of containment configuration 1 (figure 3) and the three-component configuration in the reply filed on 4/27/06 is acknowledged. The traversal is on the ground(s) that it is not a burden. This is not found persuasive because applicant arguments are not commensurate with a proper response for an election of species requirement. The election of species requirement stated:

"Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention."

It is further noted that it would require differing search strategies for the non-elected species which are not required for the elected species placing a burden on the Examiner. The requirement is still deemed proper and is therefore made FINAL

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 114-116 and 127-129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding said claims, it is unclear what limitation is implied, structural or functional, when an "eccentricity is demonstrated". It is further unclear if these limitations read on the elected embodiment.

Allowable Subject Matter

Claims 130 and 131 are allowed.

Claim 109 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 101-108, 110-122, 124-129 are rejected under 35 U.S.C. 102(a) as being anticipated by Merete (DE 20011728, applicant submitted 10/25/04).

Merete teaches:

101, (New) A containment system comprising:

(a) a shell (5), the shell comprising a cavity and an outside surface and including at least one opening on the outside surface providing access to the cavity;

b) a liner (4) (or implant structural member), the liner comprising:

an outer surface;

a lip; and

an inner surface, the inner surface forming a cavity and including a web (interpreted as the portion which continues past the hemisphere line which acts to lock the head within the liner), wherein the web extends around a portion of the lip (which is included in continuing around the entire lip);

(c) an implant stem head (1), the implant stem head comprising:

a generally spherical body having a surface configured to correspond to the web enabling the implant stem head to be inserted into the liner when the implant stem head is in a first orientation; and

a cavity (2); and

(d) a separate femoral stem component (inherent) which may be inserted into the cavity of the implant stem head,

wherein the shell may be received by an acetabulum, and

wherein the liner may be received in the cavity of the shell, and

wherein the web allows the implant stem head to be inserted into the cavity of the liner when the implant stem head is oriented in the first orientation and constrains the implant stem head within the cavity of the liner when the implant stem head is oriented in a second orientation such that the implant stem head may articulate within the liner but cannot be removed from the liner once it is attached to the stem.

Regarding at least claim 105, note the teaching of "eccentric or common axis or rotation".

It is unclear if Merete teaches a D-shaped opening. If applicant has additional information pertaining to this limitation in this reference, please forward it to the Examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 101-108, 110-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's specification in view of Schryver (5,226,917).

Applicant's specification, *Background of the invention*, teaches a hip joint prostheses comprising three-components having multiple polarity (articulating surfaces). It teaches materials such as metal, plastic, or ceramic are well know in the art. Further it teaches "a modular head and stem" are well known in the art (specification page 4, line 8). However, it fails to teach the structural member adapted to receive the head of an implant stem as claimed.

Schryver teaches a hip joint prosthesis which includes a web (the web is the extension of the element 15 beyond its equator best shown in figure 1 which inherently locks the ball) which extends around only a portion of the lip of the structural member forming a "generally" D-shaped opening. It would have been obvious to one having ordinary skill in the art to have utilized the ball and structural member (liner) configuration taught by Schryver on the known prior art embodiments having a modular head (with cavity) and stem such that the ball member is shaped to pass through the socket opening at one particular orientation for fitting the parts together, but once in place and orientated in normal positions of use the ball member cannot be removed from the socket to prevent dislocation of the joint.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bes

A handwritten signature in black ink, appearing to read 'BSN', with a long horizontal line extending to the right.

BRUCE SNOW
PRIMARY EXAMINER